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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/719,055

11/21/2003

John M. Williams

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9135

21005

7590

08/26/2008

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,055

Applicant(s)

WILLIAMS, JOHN M.

Examiner

SHIRLEY V. GEMBEH

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/CB/CIC)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/4/08 has been entered.

The response filed on **4/4/08** presents remarks and arguments to the office action mailed on **11/01/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 9/04/07 is acknowledged and has been reviewed.

Status of Claims

Claims 1-28 are pending. Claims 1-2, and 24-28 are currently amended.

Withdrawn Claim Rejections - 35 USC § 102

Claim 1-28 rejected under 35 U.S.C. 102(a) as being anticipated by Sedona et al. WO 01/87849 is withdrawn as the claims no longer anticipates the reference.

Maintained Claim Rejections-35 USC § 103

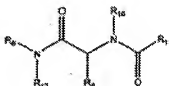
Claims 1-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sneddon et al. WO 01/87849 taken with Sviland et al J. Clin. Pathology 1999, 52:910-913 in view of Jamieson et al. (Transplant Int. (1991) 4:67-71).

Applicant argues that even though the cited references include a teaching regarding GVHD (graft versus host disease) neither one or combination of the prior art teach inhibition of transplant rejection. See page 25 of remarks five lines from the bottom. Applicant further relies on Exhibit E (Hutchinson) which teaches that chronic rejection (including declining graft function transplant vasculopathy, graft loss, and patient death) is strongly associated with high producer of TGF-beta 1 genotype. Applicant further emphasizes that compound 1 has shown evidence of inhibiting chronic rejection in mouse and they have now discovered that the compounds are effective in preventing chronic transplant.

In response, careful consideration has been given to Applicant's remarks, however in the showing of unexpected result there must be (i) the showing must be truly unexpected, (ii) it must be commensurate in scope with the claims and (iii) a direct showing of comparison with the closest prior art).

The rejection is therefore maintained as there is no showing that is commensurate in scope with the claims.

Sneddon discloses current claims 1 and 2, a method of inhibiting tissue transplant, as graft versus host disease, (see page 14, line 30), administering the



compound of formula I

Sviland et al. teach GVHD is a complication following bone marrow transplantation (see abstract, wherein (tumor necrosis factor-alpha)TNF- α are important mediators of the cellular damage. (see abstract also).

Jamieson et al. teach that GVHD is a solid organ transplantation effect. The claims recite transplantation of an organ, tissue or cell (see abstract-highlighted sec.). This is well within the claim limitation.

Applicant argues that none of the references cited teach inhibition of transplanted organs in a subject in need thereof.

In response, this is found unpersuasive, the claims are given the broadest claim interpretation. That is a method of inhibiting rejection of a transplanted organ, cell or a tissue. Analyzing the claim interpretation as follows: GVHD the bone marrow rejects the host. The rejection is maintained for the same reason given above.

Withdrawn Double Patenting

Claims 1-26 provisionally rejected under the judicially created doctrine of double patenting over claims 1-20 of copending Application No. 10/719,701 (recently allowed) is withdrawn, a terminal disclaimer has being filed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/SVG/
8/12/08

